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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,693	01/29/2004	Shaw G. Fox	17050/1098007	5585

7590 01/24/2006
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EXAMINER

JUNG, UNSU

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/767,693	Applicant(s) FOX, SHAW G.	
	Examiner Unsu Jung	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 11,12,17,20 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment of specification in the reply filed on December 1, 2005 has been acknowledged and entered.
2. Applicant's amendment of claims 1, 4-9, 17, 20, and 21 in the reply filed on December 1, 2005 has been acknowledged and entered.
3. Claims 1-26 are pending.

Oath/Declaration

4. Receipt is acknowledged of a new declaration in the reply filed on December 1, 2005.

Specification

5. Applicant's arguments, see p9, filed on December 1, 2005, with respect to the use of trademark in the specification have been fully considered and are persuasive. The objection of specification with respect to the use of trademarks CLINITECK® and MULTISTIX® has been withdrawn.

Claim Objections Withdrawn

6. Applicant's arguments, see p9, filed on December 1, 2005, with respect to the objections of claims 4-9, 17, 20, and 21 have been fully considered and are persuasive. The objections of claims 4-9, 17, 20, and 21 have been withdrawn.

Rejections Withdrawn

7. Applicant's arguments, see pp9-10, filed on December 1, 2005, with respect to the rejection under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 1, 5, and 21 under 35 U.S.C. 112, second paragraph has been withdrawn.

Claim Objections

8. Claims 11, 12, 17, 20, and 21 are objected to because of the following informalities: a comma is needed preceding the word "wherein" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 1-21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1 and 2 recite the limitation "the analysis" in line 1. There is insufficient antecedent basis for this limitation in the claim.

12. The term "substantially" in claim 12 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The limitation of "parallel to one another" has been rendered indefinite by the use of the term "substantially."

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1- 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Crosby (U.S. PG Pub. No. US 2003/0124738, Filed May 1, 2001).

Crosby anticipates instant claims by teaching a test for an analysis of one or more analytes in a fluid test sample, the test comprising:

- a carrier of an absorbent material (substrate/test strip, Fig.'s 1 and 2);
- said carrier exhibiting light reflectance within a first predetermined spectral range (Fig.'s 1 and 2);
- a plurality of test fields (test zones) on a surface of the carrier (p3, paragraph [0028] and Fig's 1 and 2);

wherein the test fields include a plurality of test field materials reactive with one or more analytes (p3, paragraph [0028]) and exhibiting light reflectance with a second predetermined spectral range (pp2-3, paragraph [0021]), the first and second predetermined spectral ranges being distinguishable from one another (bar codes, p2, paragraph [0017]), the plurality of test fields being disposed in spaced relation to one another on the carrier (Fig.'s 1 and 2), gaps between the test fields exhibit light reflectance within the first predetermined spectral (p2, paragraph [0017]), the gaps and the test fields having relative sizes, which are optically discernable (p2, paragraph [0017] and pp2-3, paragraph [0021]), and the relative sizes forming a coded sequence that correlates to information relating to the test (p2, paragraph [0017] and pp2-3, paragraph [0021]).

With respect to claim 3, Crosby teaches the test of claim 2, wherein the test fields comprise test pads (pp2-3, paragraph [0021]). According to the current specification

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(p8, lines 12-24), the term "test pads" can be of conventional construction with test pads fabricated from commonly used test field material, which are reactive to analytes.

With respect to claim 4, Crosby teaches the test of claim 2, wherein the at least one response within a range of responses comprise a reflectance within a predetermined spectral range (pp2-3, paragraph [0021]).

With respect to claim 5, Crosby teaches the test of claim 2, wherein strength of the at least one response is proportional to the relative size of the test field (pp2-3, paragraph [0021]).

With respect to claim 6, Crosby teaches the test of claim 2, wherein each of the gaps is configured to generate at least one other response within another range of responses to a light incident thereon, the at least one other response being proportional to the relative size of the gap (p2, paragraph [0017]).

With respect to claim 7, Crosby teaches the test of claim 6, wherein the at least one other response comprises an absorption of light incident thereon. The test of Crosby teaches gaps comprising a bar code, which comprises a printed strips of varying widths and it would be obvious to one of ordinary skill in the art to realize that the printed strips of varying widths (Fig.'s 1 and 2) on the test strip of Crosby would inherently possess the characteristic to absorb light.

With respect to claim 8, Crosby teaches the test of claim 6, wherein said at least one other response within a range of other responses comprises a reflectance within a predetermined spectral range (pp2-3, paragraph [0021]).

With respect to claim 9, Crosby teaches the test of claim 6, wherein said at least one response within a range of responses comprises a reflectance within a predetermined spectral range and the at least one other response within another spectral range of responses comprises a reflectance within another predetermined spectral range (Fig.'s 1 and 2).

With respect to claim 10, Crosby teaches the test of claim 2, wherein the substrate comprise a carrier fabricated from an absorbent material (pp2-3, paragraph [0021]).

With respect to claim 11, Crosby teaches the test of claim 2, wherein the substrate is elongated, having a longitudinal axis (Fig.'s 1 and 2).

With respect to claims 12 and 13, Crosby teaches the test of claim 11, wherein the gaps are elongated and extend substantially parallel to one another in a direction traverse to the longitudinal axis and the predetermined sizes comprise width dimensions of each of the gaps and the test fields, in a direction parallel to the longitudinal axis (Fig.'s 1 and 2).

With respect to claims 14-16, Crosby teaches the test of claim 13, wherein the coded sequence is defined by a combination of the relative widths of the gaps (p2, paragraphs [0017] and [0018]) and test fields (pp2-3, paragraph [0021]).

With respect to claim 17, Crosby teaches the test of claim 2, wherein the substrate is fabricated from a material, which allows the one or more analytes and labeled antibodies specific thereto to flow through it along with the fluid test sample (p1,

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paragraph [0007]) and to form analyte/labeled antibody conjugate, which can be captured in a specific capture zone of the test (p3, paragraph [0022]).

With respect to claims 18 and 19, Crosby teaches the test of claim 2, wherein the predetermined sizes comprise more than one optically discernable sizes (p4, claim 5).

With respect to claim 20, Crosby teaches the test of claim 2, wherein the information comprises an identification of one or more analytes, for which the test is designed to test (p1, paragraph [0010]).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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17. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby (U.S. PG Pub. No. US 2003/0124738, Filed May 1, 2001) in view of Lappe (U.S. Patent No. 6,036,092, Mar. 14, 2000).

Crosby teaches test for an analysis of one or more analytes in a fluid test sample as comprising a coded sequence that correlates to information relating to the test discussed above. However, Crosby fails to teach a test, wherein the information comprises information relating to a production batch, from which the test was obtained, and a date of manufacture of the test.

Lappe teaches that it is often desirable or advantageous (column 6, lines 57-61) to have items such as production batch numbers and a date of manufacture of a test strip as those skill in the art will recognize (column 6, lines 50-53). As the identification information (bar code), for the most part, will generally be fixed at the time of the manufacture (column 6, lines 53-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include test of Crosby with identification information such as in the form of a bar code relating to a production batch numbers and a date of manufacture of a test strip as taught by Lappe as it is often desirable or advantageous to have items such as production batch number and a date of manufacture associated with a test strip.

Response to Arguments

18. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. No claims allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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01/20/06